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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/449,817	11/26/1999	Mitchell S. Steiner	P-2762-US1	6736

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EXAMINER	
SCHNIZER, HOLLY G	

ART UNIT	PAPER NUMBER
1656	

DATE MAILED: 12/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/449,817	STEINER ET AL.	
	Examiner	Art Unit	
	Holly Schnizer	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,7,10,11,18-27,55,56,59 and 60* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,7,10,11,18-27,55,56,59 and 60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 July 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

The Response filed 9/21/05 has been received and considered. Claims 1, 7, 10-11, 18-27, 55-56, 59-60 are currently pending and have been considered in this Office Action.

Priority

As previously noted, the instant application is granted the benefit of priority for the U.S. non-provisional Application No. 09/302,457 filed on April 29, 1999; however, the elected subject matter has priority to the filing date of the instant application, November 26, 1999.

Applicant argues that SEQ ID NO:1 in the current application is contained within the sequence of SEQ ID NO:5 of US application Serial Number 09/302,457 and that the amino acid sequence translated from SEQ ID NO:1 shares a region of 99% identity to the amino acid sequence translated from SEQ ID NO:5. This argument has been considered but is not deemed persuasive because 99% identity between the translated sequences shows that the sequence disclosed in the instant application has a different nucleotide sequence than that of the priority application. Even if it is a difference in a single nucleotide, it is a different sequence that was not disclosed in the priority application. Thus, the elected subject matter has priority only to the filing date of the instant application.

Sequences

A paper copy of a sequence listing with seven sequences and a statement that the paper copy and CRF are the same was filed with the Response on 9/21/05. However, a sequence copy in computer readable format was not found to be associated with the file. Thus, the sequence listing as filed on August 14, 2001, which complies with the sequence rules is considered for purposes of this Office Action. Applicants must file a copy of the CRF, a paper copy, and a statement that the same. In addition, as stated in the previous Office action, an alignment of the coding DNA and the added amino acid sequence should be included to clearly show support and the lack of new matter.

Withdrawn—Objections to the Specification

Objection to the Specification for containing confusing reference materials is withdrawn in light of the amendment to the Specification.

The objection to the Abstract is withdrawn in light of the amendment.

Maintained—Objections to the Specification

The Specification is objected to for its reference to SEQ ID NO:7 as amended on page 83. The submission of the paper copy of a sequence listing does not comply with the Sequence rules because the submission did not appear to include a CRF. The

sequence listing filed on August 14, 2001, which does comply with the sequence rules, includes only 6 sequences. Thus, the objection is maintained.

Withdrawn—Claim Objections

The objection of Claim 1 for improper language ("encoding for") is withdrawn in light of the amendment.

The objection of Claim 7 for failing to further limit the claim from which it depends is withdrawn in light of the amendment.

The objection of Claim 26 for failing to further limit the claim from which it depends is withdrawn in light of the amendment.

The objection of Claims 54-56 and 60-61 for failing to further limit the claim from which they depend is withdrawn in light of the amendment to these claims making them independent.

The objection of Claim 62 for failing to further limit the claim from which it depends is withdrawn in light of its cancellation.

Rejections Withdrawn

The rejection of Claim 16 under 35 U.S.C. 112, second paragraph as being indefinite for the phrase, "sequence complementary to" is withdrawn in light of the cancellation of the claim.

The rejection of Claim 22 under 35 U.S.C. 112, second paragraph as being indefinite for an unclear antecedent basis is withdrawn in light of the amendment.

The rejection of Claims 61 and 63 under 35 U.S.C. 112, second paragraph as indefinite as to the metes and bounds of "analog" is withdrawn in light of the cancellation of these claims.

The rejection of Claims 61-63 under 35 U.S.C. 112, first paragraph, written description is withdrawn in light of the cancellation of the claims.

The rejection of Claims 12-15 and 62-63 under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter is withdrawn in light of the cancellation of these claims.

The rejection of Claims 12 and 13 under 35 U.S.C. 102(b) as being anticipated by Hillier et al. is withdrawn in light of the cancellation of these claims.

The rejection of Claims 12-15 under 35 U.S.C. 102(b) as being anticipated by Talisman et al. is withdrawn in light of the cancellation of these claims.

The rejection of Claims 62-63 under 35 U.S.C. 102(b) as being anticipated by Hillier et al. or Talisman et al. is withdrawn in light of the cancellation of these claims.

The rejection of Claims 12-15, 54, and 61-63 under 35 U.S.C. 102(e) as being anticipated by Ni et al. (USPAP 2002/0064818) is withdrawn in light of the cancellation of these claims. It is noted that this rejection is maintained for Claim 55 for the reasons cited below.

Rejections Maintained

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

> art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 7, 10-11, 18-27, 55-56, and 59-60 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants argue (pp. 16-17 of the Response filed 9/21/05) that a portion of the sequence encoding human p-Hyde protein (SEQ ID NO:1) is disclosed and has been described structurally. This argument has been considered but is not deemed persuasive because as stated in the previous Office Action, the issue at hand is that *only a portion of the full-length gene* encoding human p-Hyde protein is disclosed in the Specification and not how well the Specification describes the disclosed *portion*. The claims drawn to a nucleic acid molecule encoding the human p-Hyde protein encompasses the full length gene, the sequence of which has not been disclosed and could not be predicted by those of skill in the art.

Applicants argue that they have also defined the human p-Hyde protein functionally. This argument has been considered but is not deemed persuasive because the Specification does not provide any relationship between structure and function. As stated in the previous Office Action with respect to Claims 55-56, currently pending, an issue here (in addition to the lack of a full-length gene) is that these claims are drawn to a genus of different sequences without any function. To fully describe a genus of genetic material, which is a chemical compound, applicants must 1) fully

describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus and 2) identify the common characteristics of the claimed molecules, e.g. structure, physical and/or chemical characteristics, functional characteristics coupled with a known or disclosed correlation between structure and function, or a combination of these. First, Applicant has not described a species; a full-length nucleotide sequence that would encode SEQ ID NO:1 (the full length human p-Hyde gene). Second, Applicants have not provided what part of the sequence is essential to the function of the encoded protein. The specification describes p-Hyde functionality as the ability to induce cell death susceptibility in a cancer cell but does not describe what parts of the p-Hyde sequence are essential or non-essential to that function. Moreover, Applicants have not fully described a genus that has sequence identity limitations in the absence of functional limitations.

Applicants further argue that the Specification provides guidance and working examples to practice the claimed invention (p. 17, 3rd paragraph of Response) and that sufficient support exists for claims directed to nucleic acid sequences encoding human p-Hyde proteins in view of the guidance, working examples, the degree of skill in the art, and the state of the art. It appears that Applicants are arguing that the claims are enabled (see also p. 16, 2nd to last paragraph). However, this is a "written description" rejection, rather than an enablement rejection under 35 U.S.C. 112, first paragraph. Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1, "Written Description" Requirement, Federal Register, Vol. 66,

No. 4, pages 1099-1111, Friday January 5, 2001. *Vas-Cath Inc. V. Mahurka*, 19 USPQ2d 1111, states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention, for purposes of the "written description" inquiry, is *whatever is now claimed*" (see page 1117). Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 1115).

Thus, the rejection of these claims is maintained for reasons cited above and in the previous Office Actions.

Claims 1, 7, 10-11, 18-27, 55-56, and 59-60 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and/or substantial asserted utility or a well-established utility.

Applicant argues that due to similar differential expression and sequence similarity, the partial human sequence disclosed must function as the rat sequence disclosed. This argument has been considered but is not deemed persuasive. What is disclosed in the instant application is a portion of human p-Hyde. No description is found of what portion of rat p-Hyde is responsible for the experimentally determined function of rat p-Hyde, wherein said function, by Applicant's assertion and the Examiner's agreement, would support the utility of the claimed product, human p-Hyde. Thus, it is wholly unknown if this *portion* of human p-Hyde has the rat p-Hyde function (this is because without any structure function relationship or evidence that the portion

is functional, it is not possible to predict what part of the sequence is sufficient or essential for a given function). Without evidence that the disclosed portion of human p-Hyde has the same function as the rat full-length p-Hyde, the assumption that the disclosed portion of human p-Hyde has the same function is not convincing. Applicants argue that the partial human sequence shares a region of 84% identity with the sequence encoding the rat protein. However, there is no evidence or way to predict that this region (or the entire partial sequence) on its own is sufficient for activity. While the full-length rat protein may have a particular function, there is no evidence of what smaller parts of that sequence are required for activity.

A part of the previous rejection is repeated below for completeness:

> "The instant claims are drawn to a nucleic acid sequence (p-Hyde gene) encoding a human p-Hyde protein. A p-Hyde protein from rat is characterized in the instant specification; the experiments presented for the rat protein indicate that rat p-Hyde has the ability to induce cell-death-susceptibility in a cancer cell. It can be reasonably assumed that other p-Hyde proteins from other mammals will possess the same, or closely related activity. The utility of the claimed invention relies on the activity proposed for the rat protein.
>
> The utility of the rat protein and gene cannot be translated into utility for the human protein and gene because it is unclear that the sequences are related. The instant specification discloses cDNA sequences from human (SEQ ID NO:1) and rat (SEQ ID NO:3) encoding a "p-Hyde" protein. These DNA sequences share a region of 84% identity (see attached alignment). The rat protein is 489 amino acids long from a cDNA open reading frame of 1467 base pairs. The human protein is 186 amino acids long from a cDNA open reading frame of 637 base pairs (disclosed in SEQ ID NO: 1 also contains non-coding regions from 1-78 and from 638-733). It is not convincing that a rat protein of 489 amino acids would have a homolog in human of 186 amino acids, especially one so dissimilar in sequence. Moreover, no structural, domain analysis of the rat sequence has been offered to demonstrate a functional domain that is retained in the shorter human sequence. Thus, without convincing evidence that the disclosed human sequence actually encodes a p-Hyde homolog, the claimed nucleic acid sequences lack a patentable utility."

Claims 1, 7, 10-11, 18-27, 55-56, and 59-60 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and/or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 55 is rejected under 35 U.S.C. 102(e) as being anticipated by Ni et al. (USPAP 2002/0064818).

Applicants argue that SEQ ID NO:1 shares 98.7% identity with the human p-Hyde sequence disclosed in priority U.S. Application No. 09/302,457 and given the priority date of this application the Ni et al. is not prior art. This argument has been considered but is not deemed persuasive for reasons cited on page of this Office Action and in previous Office Actions. The sequence of SEQ ID NO:1 of the present application does not have the benefit of priority application 09/302,457 because it has a

different sequence than the sequence of the priority application and therefore is a different sequence.

As stated in the previous Office Action (p. 14 of OA mailed 7/26/04), Ni et al. teaches a 1038 bp DNA of SEQ ID NO:17 that is a fragment of Applicants SEQ ID NO:1 having an overall sequence identity of greater than 90% (see alignment attached to previous Office Action). As noted in the previous action, the sequence taught by Ni et al. is granted priority to the earlier filing date of September 3, 1999, having been disclosed in the provisional application 60/152,315.

Conclusions

No Claims are allowable.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Holly Schnizer whose telephone number is (571) 272-0958. The examiner can normally be reached on Tuesday-Thursday from 10 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached on (571) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Holly Schnizer
December 6, 2005

NASHAAT T. NASHED PHD.
PRIMARY EXAMINER